

## **Section II (Remarks)**

### **A. Summary of Amendment to the Claims**

By the present Amendment, claims 1 and 2 have been amended and new claims 15-20 have been added. Amendment of claim 1 is supported by the language of original claim 3, as filed, and the examples of the specification. Amendment of claim 2 is supported in the specification at page 4, lines 9-10 and the examples of the specification. New claims 15-20 are supported by the examples.

No new matter within the meaning of 35 U.S.C. §132(a) has been introduced by the foregoing amendments. The amendments made herein are fully consistent with and supported by the originally-filed disclosure of this application.

By the present amendment, cancellation of claim 3 is requested, without prejudice.

Thus, upon entry of the amendments, claims 1, 2, and 4-20 will be pending, of which claims 4-14 are withdrawn.

### **B. Rejection of Claim 2 under 35 U.S.C. §112, second paragraph**

In the Office Action mailed March 10, 2009 the examiner rejected claim 2 under 35 U.S.C. §112, second paragraph as indefinite for recitation of the language "...has a mean molecular weight ranging from 5,000 to 15,000 kDa."

The examiner's attention is respectfully drawn to Section I above where claim 2 has been amended to clarify the language therein. Specifically, as amended, claim 2 recites "...has a mean molecular weight in a range of from 5,000 to 15,000 kDa." As amended, it is clear that the mean molecular weight of the claimed PGA must be within the range of 5,000-15,000 kDa. This range is supported in the specification at page 4, lines 9-10 and in Example 1 of the specification.

As amended, claim 2 is clear and meets the requirements of 35 U.S.C. §112, second paragraph. Withdrawal of the rejection is respectfully requested.

### **C. Double Patenting**

Applicants acknowledge the provisional rejection of claims 1-3 as unpatentable under the judicially created doctrine of obviousness-type double patenting, in light of: 1) claim 7 of co-pending Application No. 11/324,675, 2) claim 2 of co-pending Application No. 11/817,021, and 3) claim [no claim number

provided, claim 2 assumed] of co-pending Application No. 12/090,678. It is noted that each of these rejections is a provisional rejection, which is not properly made final until one or both of the subject applications is in condition for allowance. However, applicants respectfully disagree with the provisional rejections, and contend that pending claims 1-3 of the present application 10/520,557 are patentable in light of the pending claims of each of the cited applications.

As provided in MPEP §804.02, “[c]laims that differ from each other (aside from minor differences in language, punctuation, etc.), whether or not the difference would have been obvious, are not considered to be drawn to the same invention for double patenting purposes under 35 U.S.C. 101.” Each of the cited claims differs from claims 1-3 of the present invention such that the claims are not drawn to the same invention for purposes of double patenting.

The examiner’s attention is respectfully drawn to Section I above, where claim 1 has been amended to specify that the claimed PGA is isolated from *Bacillus subtilis* var. *chunkookhjang* (KCTC0697BP) and containing specific characteristics of the PGA so isolated.

#### U.S. Patent Application No. 11/324,675

The examiner rejected claims 1-3 over claim 7 of U.S. Patent Application No. 11/324,675, where claim 7 recites:

7.  $\gamma$ -PGA according to claim 6, having a molecular weight of about 13,000,000.

A Notice of Allowability was issued in U.S. Patent Application No. 11/324,675 on April 27, 2009. By that Notice, claims 1, 2 and 9 were allowed, and claims 6-8 were cancelled. U.S. Patent No. 7,582,466 issued from U.S. Patent Application No. 11/324,675 on September 1, 2009 with claims 1-3, corresponding to original each of claims 1, 2, and 9, respectively.

Claim 7, on which the provisional rejection of claims 1-3 of the present application was based, was cancelled from U.S. Patent Application No. 11/324,675 at the time of allowance. Pending claims 1-3 of the present application are patentable in light of issued claims 1-3 of U.S. Patent No. 7,582,466, reciting a biologically pure culture of a strain of *Bacillus subtilis* var. *chunkookhjang* (KCTC0697BP). The provisional rejection of claims 1-3 in view of claim 7 of U.S. Patent Application No. 11/324,675 is therefore moot. Withdrawal of the rejection is respectfully requested.

#### U.S. Patent Application No. 11/817,021

The examiner also rejected claims 1-3 over claim 2 of co-pending Application No. 11/817,021. In the most recent Office Action Response, submitted to the USPTO on April 15, 2009, claim 2 was cancelled by the applicants. However, new claim 13 has been added, where claim 13 recites:

13. The vaccine composition according to claim 3, wherein the molecular weight of poly-gamma-glutamic acid is in a range of from 10kDa to 10,000 kDa.

Claim 3, from which claim 13 depends, recites a vaccine composition comprising poly-gamma-glutamic acid as an element thereof. Therefore claim 13 also recites a vaccine composition. Accordingly, claim 13 of co-pending Application No. 11/817,021 and claims 1-3 of the present application do not “both claim a gamma-poly(glutamate) with a molecular weight of greater than 5000 kDa” as alleged by the examiner. (Office Action mailed March 10, 2009, p. 3.)

Claims 1-3 of the present application are patentable in light of the pending claims of U.S. Patent Application No. 11/817,021. Withdrawal of the provisional rejection of claims 1-3 in view of claim 3 of U.S. Patent Application No. 11/817,021 is respectfully requested.

U.S. Patent Application No. 12/090,678

The examiner further rejected claims 1-3 of the present application over a claim of U.S. Patent Application No. 12/090,678, where no particular claim number was specified. Clarification is respectfully requested.

It is assumed that the rejection is intended in light of claim 2 of U.S. Patent Application No. 12/090,678, where, as a result of the preliminary amendment filed with the application on April 18, 2008, claim 2 recites:

2. The composition according to claim 1, wherein the molecular weight of PGA is about 1 to 10,000 kDa.

However, claim 1 of U.S. Patent Application No. 12/090,678, from which claim 2 depends, recites a composition for the inhibition of hyaluronidase activity comprising PGA as an active ingredient thereof. Therefore claim 2 also recites a composition for the inhibition of hyaluronidase activity. Accordingly claim 2 of co-pending Application No. 12/090,678 and claims 1-3 of the present application do not “both claim a gamma-poly(glutamate) with a molecular weight of greater than 5000 kDa, specifically 10,000 kDa” as alleged by the examiner. (Office Action mailed March 10, 2009, p. 4.)

Claims 1-3 of the present application are patentable in light of the pending claims of U.S. Patent Application No. 12/090,678. Withdrawal of the provisional rejection of claims 1-3 in view of claim 2 of U.S. Patent Application No. 12/090,678 is respectfully requested.

#### **D. Rejection of Claims 1-3 under 35 U.S.C. § 102**

In the Office Action mailed March 10, 2009 the examiner rejected claims 1-3 under 35 U.S.C. §102(b) as anticipated by PCT Publication No. WO 99/25864 (hereinafter “DiIorio et al.”). Applicants respectfully traverse the rejection.

Anticipation of a claim requires the disclosure in a single prior art reference of each element of the claim under consideration. (*Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987.)) The examiner’s attention is respectfully drawn to Section I above, where claim 1 has been amended, in part, to specify that the claimed PGA is isolated from *Bacillus subtilis var. chunkookhjang* (KCTC0697BP). However, it is the examiner’s position that such characteristic “does not add any structure to the claimed compound and thus does not garner patentable weight.” (Office Action mailed March 10, 2009, p. 5.) Applicants respectfully disagree.

It is well established that “[t]he structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially...where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garner*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)” (MPEP §2113; emphasis added). The PGA of claims 1 and 2 has such distinct structural and/or functional characteristics.

The examiner’s attention is respectfully drawn to the further amendment of claim 1, as set forth in Section I above. Specifically, claim 1 has been further amended to recite the characteristics of high moisture-absorption, high moisture-retention, and high Ca solubility. Such characteristics are attributable to isolation from *Bacillus subtilis var. chunkookhjang* (KCTC0697BP).

As described in the Examples of applicants’ specification, ultra-high molecular weight PGA that is isolated from *Bacillus subtilis var. chunkookhjang* (KCTC0697BP) in an optimization medium and under optimal culturing conditions is shown to have high moisture-absorbing properties, high moisture-retaining properties, and high Ca solubility, as compared to PGA with molecular weights of 600 kDa (Example 2), 1,000 kDa (Example 3), and 2,000 kDa (Example 3).

Since DiIorio et al. does not describe an ultra-high molecular weight PGA isolated from *Bacillus subtilis* var. *chunkookhjang* (KCTC0697BP) demonstrating the characteristics of high moisture-absorption, high moisture-retention, and high Ca solubility as set forth in claims 1-2, DiIorio et al. does not anticipate the claimed invention. Accordingly, withdrawal of the rejection of claims 1-3 under 35 U.S.C. § 102(b) as being anticipated by DiIorio et al. is respectfully requested.

#### **E. Fees Payable for Added Claims**

By the present Amendment 3 new independent claims have been introduced, beyond the number for which payment was previously made. Small entity fees payable for such added claims are calculated as follows:

$$4 \text{ total independent claims} - 3 \text{ independent claims} = 1 \times \$110.00 = \underline{\$110.00}$$

Payment of such fees is being made by on-line credit card authorization at the time of EFS submission of this Response.

#### **CONCLUSION**

Based on the foregoing, all of applicants' pending claims 1, 2 and 15-20 are patentably distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing and to responsively issue a Notice of Allowance.

The time for responding to the March 10, 2009 Office Action without extension was set at three months, or June 10, 2009. Applicants hereby request a three month extension of time under 37 CFR § 1.136 to extend the deadline for response to September 10, 2009. Payment of the extension fee of \$555.00 specified in 37 C.F.R. § 1.17(a)(3), as applicable to small entity, is being made by on-line credit card authorization at the time of EFS submission of this Response. Should any additional fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any issues require further resolution, the examiner is requested to contact the undersigned attorneys at (919) 419-9350 to discuss same.

Date: September 10, 2009

Respectfully submitted,  
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<p><b>The USPTO is hereby authorized to charge any deficiency or credit any overpayment of fees properly payable for this document to Deposit Account No. 08-3284</b></p>
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